Update on EPA's Pesticide Program Activities

Beltwide Cotton Conferences

January 5, 2021

Office of Pesticide Programs
Michael Goodis, Acting Deputy Director

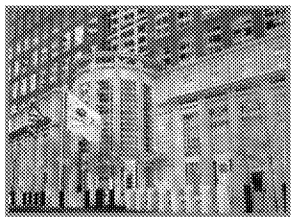
Good morning. I'm pleased to be here with you today at the Beltwide Cotton Conferences. Thank you for the invitation.
EPA recognizes the importance of effective collaboration with our co-regulators in achieving our mission of protecting public health and the environment.
We value our strong partnerships, not only for implementing and enforcing regulatory decisions, but also for the collaboration and input you provide as we work through challenging issues.
Whether it's actively engaging with EPA on a number of high priority topics, ranging from electronic improvements in our registration and labeling processes, examining possible causes of dicamba offsite crop damage to develop a mitigation plan to reduce the potential for off-target movement, or working in a concerted effort to combat the SARS-CoV-2, the virus that causes COVID-19, the value of effective stakeholder participation is incalculable in operating a regulatory program such as ours.

Discussion Topics

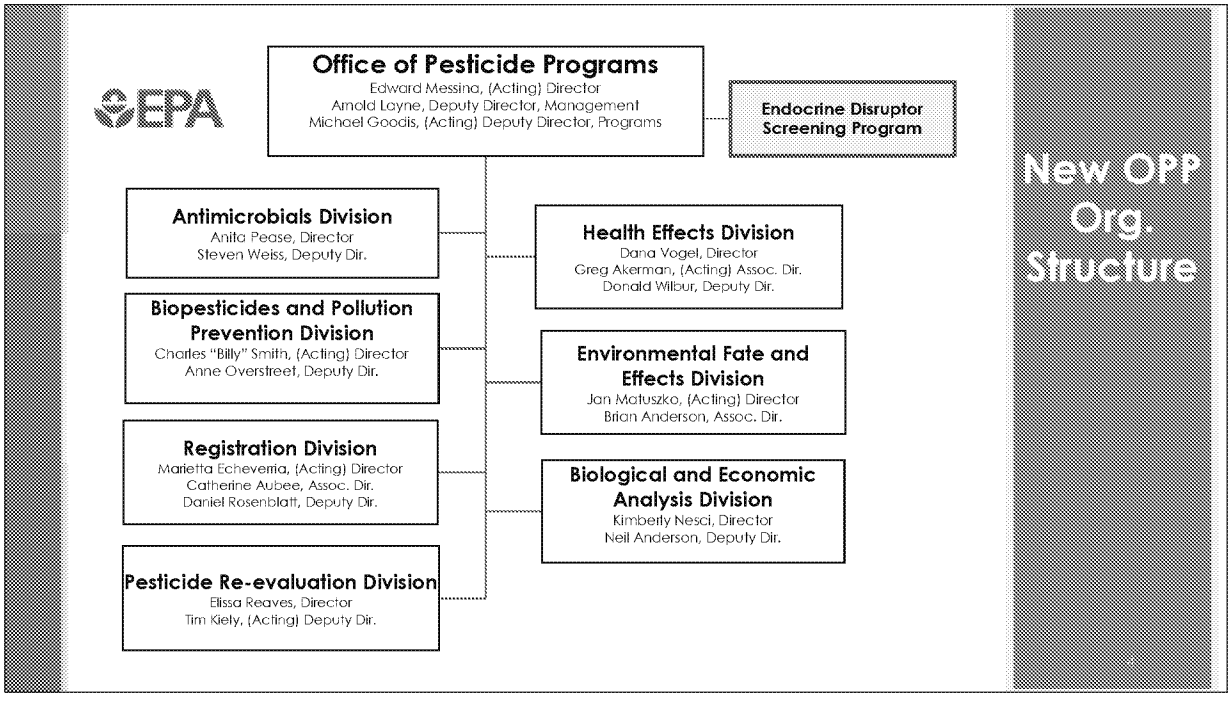
- Office of Pesticide Programs Overview
- FY20 Registration Highlights
  - Dicamba
- FY20 Registration Review Updates
- Risk Management
- Endangered Species Highlights

Office of Pesticide Programs (OPP)

- **OPP's Structure and Resources:**
  - One of largest program offices at EPA Headquarters within the Office of Chemical Safety and Pollution Prevention (OCSPP)
  - 7 Divisions containing ~ 600 employees
  - Staff are primarily in Washington, DC area (Arlington, VA) but some pesticide liaisons reside in the 10 regional offices



- **OPP Staff:**
  - Highly educated and technically trained; most have scientific backgrounds including biologists, chemists, toxicologists, geneticists, weed scientists, wildlife biologists, entomologists, plant pathologists, statisticians
  - Support staff include employees with communications, regulatory, financial, information management and computer specialties


EPA
Office of Pesticide Programs
Edward Messina, (Acting) Director
Arnold Layne, Deputy Director, Management
Michael Goodis, (Acting) Deputy Director, Programs
Endocrine Disruptor Screening Program
Antimicrobials Division
Anita Pease, Director
Steven Weiss, Deputy Dir.
Biopesticides and Pollution Prevention Division
Charles "Billy" Smith, (Acting) Director
Anne Overstreet, Deputy Dir.
Registration Division
Marietta Echeverria, (Acting) Director
Catherine Aubee, Assoc. Dir.
Daniel Rosenblatt, Deputy Dir.
Pesticide Re-evaluation Division
Elissa Reaves, Director
Tim Kiely, (Acting) Deputy Dir.
Health Effects Division
Dana Vogel, Director
Greg Akerman, (Acting) Assoc. Dir.
Donald Wilbur, Deputy Dir.
Environmental Fate and Effects Division
Jan Matuszko, (Acting) Director
Brian Anderson, Assoc. Dir.
Biological and Economic Analysis Division
Kimberly Nesci, Director
Neil Anderson, Deputy Dir.
New OPP Org. Structure

OPP's Responsibilities

- Protect human health and the environment
- Ensure any pesticide residues on food and feed are safe
- Ensure pesticide users have information (*e.g.*, clear label) that allows for proper use
- Ensure decisions reflect the best science and policy judgments
  - Evolving science
  - Endangered species, pollinators, endocrine disruption, human studies are important and challenging science and policy issues
- Meet market needs
  - Industry has timely decisions for their products
  - Farmers and other consumers get products they need
- Meet milestones and statutorily mandated deadlines for regulatory actions

FY20 Registration Highlights

EPA FY20 Registration Highlights

- Registered 16 new active ingredients
- Registered 163 new uses of existing pesticides
- 68 Section 18 emergency exemption decisions
- Overall, 2,385 PRIA actions completed
  - 98% on-time completion rate
  - 34% renegotiation rate

EPA Dicamba 2020 Registration Decision

- EPA's October 27, 2020 dicamba registration decision concerned three products containing dicamba and allowing for post-emergent, over-the-top (OTT) use.
- Two new products (Engenia and XtendiMax) were registered.
- The third product (Tavium) was granted an extension of its existing registration.

EPA Registration #	Company Name	Product Name
7969-472	BASF	Engenia Herbicide
264-1210	Bayer	XtendiMax With VaporGrip Technology
100-1623	Syngenta	A21472 Plus VaporGrip Technology (Alternate Brand Name = Tavium)

Dicamba 2020 Registration Decision

Reaching a Decision:

- Statutory Requirements
  - ESA No-effects determination
  - FIFRA risk-benefit decision
- Following the Science
- Balancing the Impacts of Control Measures
  - All control measures to reduce incidents are likely to impact user's ability to use the product
  - Conversely, measures to provide farmers with flexibility are more likely to negatively impact non-users

EPA Highlights of the 2020 Dicamba Decision

- Labels allow use only on dicamba-tolerant (DT) cotton and soybeans
- Revised in-field buffer distances
- Mandatory use of volatility reducing agent
- Calendar cutoff dates for making applications
- Updated ESA finding
- 5-year expiration dates for the registrations
  - Expiration date for the 2020 dicamba registrations: 12/20/25

2020 Dicamba Registrations: Approved Uses

- For use ONLY on DT cotton and DT soybeans
  - OTT use
  - Includes pre-emergent and post-emergent applications to DT-crops
- Not for use on any non-DT crops
  - New to the 2020 labels
- List of states allowing use is unchanged from 2018

2020 Dicamba Registrations: Application Timing

- The 2020 federal labels introduce mandatory calendar cutoff dates for applications:
  - Dicamba-tolerant **soybeans**: DO NOT apply later than **June 30**
  - Dicamba-tolerant **cotton**: DO NOT apply later than **July 30**
- Calendar dates are more enforceable than growth stages
- Inversion, rainfall, wind speed, & sunrise/sunset timing restrictions are unchanged from 2018 labels

Volatility Reducing Agent (VRA) Requirement

- All applications of Engenia, Tavium, and XtendiMax must include a VRA in the tank mix
- The purpose of the VRA is to reduce volatility
- Applicators can use any VRA that has been tested and is listed as approved on the registrant companies' websites
- So far registrants have developed and tested two VRAs
  - BASF: SENTRIS; Bayer: VaporGrip Xtra
- Each registrant company is required to maintain a website of acceptable VRAs
- Registrants are also required to ensure that sufficient quantities of VRAs are available in channels of trade

*Note: In this registration decision, "volatility reducing agent," or "VRA" = "pH Buffering Agent."

Required Buffer Distances

- In counties without endangered and threatened species concerns:
  - A downwind, in-field buffer distance of **240 ft** is required for all applications
- In counties with endangered and threatened species concerns:
  - Listed Species Protection Requirement of a **310 ft** downwind in-field buffer and an omnidirectional in-field buffer of **57 ft** for all applications.
- How do I know which type of county I am in?
  - You must check Bulletins Live! Two (BLT) prior to making an application.
  - Labels provide instructions on how to access Bulletins Live! Two.

With Optional Hooded Sprayers

- Hooded sprayer systems have the potential to reduce spray drift during pesticide applications
- If using a qualified hooded sprayer, the buffer distances for applications to soybeans may be reduced
  - For counties without listed species concerns, buffer distances are reduced from **240 to 110 ft**
  - For counties with listed species concerns, buffer distances are reduced from **310 to 240 ft**
- No exemption from omnidirectional in-field buffer of **57 ft** for ESA counties
- Only hooded sprayers that have met EPA's performance standard and are specified on the appropriate registrant's website are eligible for reduced buffer distances
- EPA notes there is currently limited availability of hooded sprayers but wishes to encourage the use of drift reduction technology of various forms

EPA Other Types of Requirements

- Training
  - In addition to certified applicator training, applicators of these products must complete annual, dicamba-specific training
- Recordkeeping
  - Requirements are listed on the labels
  - VRA use is one new component of the 2020 list of recordkeeping requirements
- Herbicide resistance management
  - Especially important because confirmed detections of dicamba-resistant Palmer amaranth since 2019

EPA State Modifications to Labels

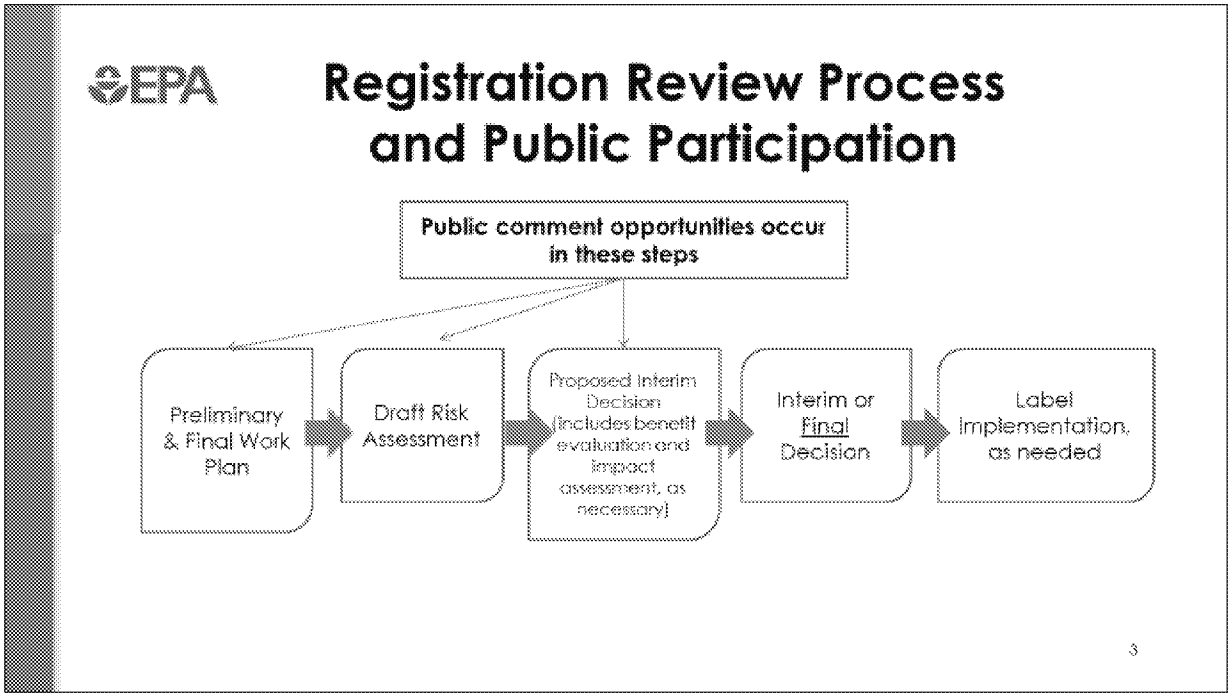
- FIFRA Section **24(a)** allows a state to regulate pesticides **more restrictively** than EPA under the state's own authority
- FIFRA Section **24(c)** authorizes states to issue registrations for **additional uses** of federal registrations to meet special local needs
- If states wish to impose further restrictions on the dicamba products, they should do so under 24(a)

EPA guidance website on 24(c) registrations:
https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations

FY20 Registration Review Highlights

Registration Review

- Section 3(g) of FIFRA requires review of each registered pesticide every 15 years to ensure that each pesticide registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.
- The first round of registration review began in October 2007 and all 726 “cases,” encompassing over 1,100 pesticide active ingredients, must be completed by the statutory deadline of October 1, 2022.
- The future scope of registration review will be revolving, as chemicals need to go through the process again no later than 15 years after the date on which the initial registration review is completed, or the date the chemical was registered.



Section 3(g) of FIFRA requires review of each registered pesticide every 15 years to ensure that each pesticide registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.

The first round of registration review began in October 2007 and all 726 "cases," encompassing over 1,100 pesticide active ingredients, must be completed by the statutory deadline of October 1, 2022.

The future scope of registration review will be revolving, as chemicals need to go through the process again no later than 15 years after the date on which the initial registration review is completed, or the date the chemical was registered.

EPA Registration Review Highlights

Overall Registration Review Status

- 646 draft risk assessments completed (~11% remaining)
- 551 proposed interim decisions complete (~24% remaining)
- 481 final or interim decisions complete (~34% remaining)

2020-2021 Registration Review Schedule for Draft Risk Assessments, Proposed Interim Decisions, and Interim Decisions on Conventional Cases (as of 12/11/2020)

Draft Risk Assessments	Proposed Interim Decisions	Interim Decisions
Quarter 1 FY2021 (October - December 2020)		
•Chlorothalonil •Diuron •ETO •Famoxadone •Fluometuron •Inorg. chlorates •Mancozeb •Methanearsonic acid, salts (MSMA) •Napropamide •Nicarbazin •Propiconazole •Tetraconazole	•4-Aminopyridine •Acetochlor •Chlorpyrifos •Dimethenamid •Ethofumesate •Forchlorfenuron •Novaluron •Orthophenylphenol •Oxadiazon •Picloram •Rotenone	•Acequinocyl •Clopyralid •Dithiopyr •Etridiazole •Fenpyroximate •Flonicamid •Flumetralin •Formetanate HCl •MCPB, and salts •Metolachlor & s-Metolachlor •Naphthalene •p-Dichlorobenzene •Propanil •Terbacil •Triclopyr, salts and esters

https://www.epa.gov/pesticide-reevaluation/registration-review-schedules

EPA Registration Review Highlights

Acephate

- Human Health Risk Assessment identified potential risks from:
  - Drinking water alone
  - Food alone
  - Food + drinking water
  - Residential post-application exposures
  - Occupational handler and post-application scenarios
- Ecological risk assessment identified potential risks for all taxa
- EPA plans to issue the proposed and final decisions in FY22

Registration Review Updates

Tribufos

- Human Health Risk Assessment identified potential risks from:
  - Drinking water alone
  - Food + drinking water
  - Occupational handler and post-application scenarios
- Ecological risk assessment identified potential risks for:
  - Terrestrial and aquatic plants
  - Aquatic vertebrates and invertebrates
  - Mammals
  - Birds
- EPA plans to issue the proposed and final decisions in FY22

Registration Review Updates

Pyrethroids

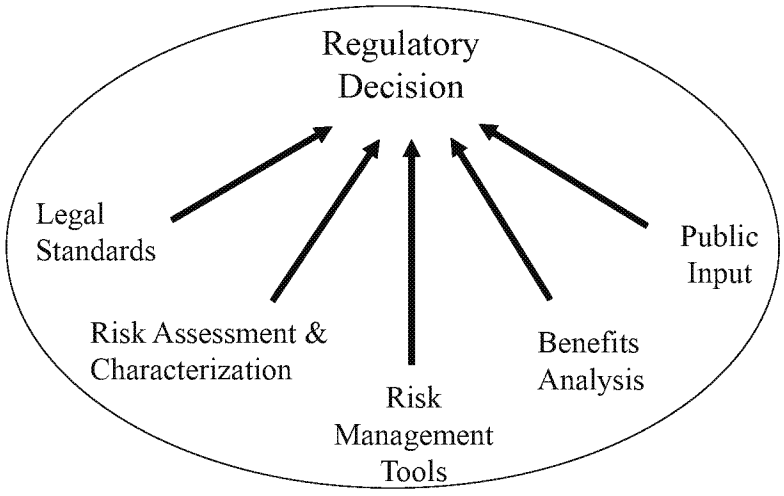
- Throughout 2020, EPA published numerous proposed interim decisions as well as some interim decisions for the pyrethroids. EPA plans to publish the remaining pyrethroid interim decisions in 2021.

Registration Review Updates

Paraquat

- EPA issued a proposed interim decision for paraquat with new measures to reduce risks, to better to protect human health and the environment.
  - EPA plans to issue an interim decision later FY21
- EPA has taken steps outside of the standard registration review process to ensure paraquat is used in a manner that is safe and consistent with the label directions:
  - Includes a safety awareness campaign and changes to labels and product packaging to stop improper uses.
  - Specialized training for certified applicators who use paraquat was released last year to ensure that the pesticide is used correctly.

Risk Management



Risk Management

- **Risk Management Goals**
  - Ensure that registered pesticides (continue to) meet the statutory standards for protecting human health and the environment
  - Effectively assess, manage and mitigate risks based on best available science and policy, involving stakeholders and the public
- **Risk Managers**
  - Consider the results of the risk assessments
  - Have an understanding of the benefits of a pesticide, as well as alternative pesticides that are already registered
  - Develop measures needed to mitigate any identified risks
  - Negotiate with registrants regarding potential modifications to the product or labeling that must be made to mitigate risk

Endangered Species Highlights

Endangered Species Act

- Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the "actions" they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (jointly the Services).
- For the Office of Pesticide Programs, the "actions" we authorize are the sale, distribution, and use of pesticides according to the product labeling.

ESA Obligations

- **Basic Process for ESA Assessments:**
  - EPA makes "effects determination" for individual listed species in a biological evaluation (BE).
  - If EPA concludes:
    - No effect (NE) – no consultation is required
    - Not likely to adversely affect (NLAA) – informal consultation with concurrence from Services is required – and formal consultation may be required if Services do not concur
    - Likely to adversely affect (LAA) – formal consultation is required, and the Services issue a Biological Opinion (BiOp) to determine if there is jeopardy
- Nationwide consultations must consider direct/indirect effects to 1850 listed species and 600+ designated critical habitats.

Endangered Species Act: Improving Coordination

- In January 2018, EPA, the Department of the Interior and the Department of Commerce signed a Memorandum of Agreement creating a Working Group to provide recommendations for improving the ESA consultation process for pesticide registration and registration review.
  - The Working Group will provide recommendations to EPA, FWS and NMFS leadership on improving the ESA consultation process for pesticide registration and registration review.
- The 2018 Farm Bill established an interagency committee to better coordinate on endangered species work relative to pesticide registration activities under FIFRA.
  - Codified the MOA Group and expanded to include the Council on Environmental Quality
  - Requires regular Reports to Congress on committee's progress

Endangered Species Highlights

- Released 3 new methodologies to improve drinking water assessments
- Released revised methods to conduct Biological Evaluations (BEs) under ESA
- Released draft BEs for methomyl and carbaryl
  - Hosted public webinar on the draft BEs for methomyl and carbaryl
- Released draft BEs for glyphosate, atrazine, simazine, propazine
- Submitted 2nd ESA report to Congress, highlighting the progress achieved in creating a more efficient and effective review process of pesticide impacts under ESA
- Released final avian waiver guidance and clarification guidance regarding acceptance of fish bioconcentration studies

EPA Current Schedule for Upcoming Draft and Final Biological Evaluations

Pesticide	Draft BE Date	Final BE Date
Methomyl, Carbaryl	March 2020	March 2021
Atrazine, Simazine, Propazine, Glyphosate	November 2020	September 2021
Clothianidin, Imidacloprid[a], Thiamethoxam	June 2021	June 2022
Brodifacoum, Bromadiolone, Warfarin, Zinc phosphide	September 2023	September 2024

[a] Imidacloprid date is part of a draft settlement that is currently out for public comment and will be completed according to this schedule if the settlement is finalized.

EPA

Thank You
Questions & Answers